OFGS File: P/546-239 DIV

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Nozer M. MEHTA et al.

Date: February 9, 2001

Serial No.: Not Yet Known

Filed: Herewith

For: DIRECT EXPRESSION OF PEPTIDES INTO CULTURE MEDIA

Assistant Commissioner for Patents Washington, D.C. 20231

# PRELIMINARY AMENDMENT TO ACCOMPANYING DIVISIONAL APPLICATION UNDER 37 C.F.R. §1.53(b)

Sir:

Preliminary to the examination of the subject application, please make the following amendments a part of the record:

# In the Specification

Please amend the specification as follows:

Page 1, delete lines 3-5 and insert the following:

--This is a division of application Serial No. 09/500,009, filed February 8, 2000, now allowed, which is a division of application Serial No. 09/060,765, filed April 15, 1998, now U.S. Patent No. 6,103495, which claims priority of U.S. Provisional Application No. 60/043,700, filed April 16, 1997.--

## In the Claims

Please cancel claims 1-85, 88-90, 95 and 98-101 and amend claims 86 and 87 as follows:

86. (Amended) A method of producing an amidated peptide product comprising the steps of:

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- (a) culturing [the] <u>a</u> host cell <u>transformed or transfected with an expression vector</u> [of claim 20] in a culture medium wherein the peptide product includes a C-terminal glycine;
  - (b) recovering said peptide product from said culture medium; and
- (c) converting said peptide product to [an] the amidated peptide by converting said C-terminal glycine to an amino group, wherein

said expression vector comprises:

- (1) a coding region with nucleic acids coding for the peptide product coupled in reading frame 3' of nucleic acids coding for a signal peptide; and
- (2) a control region linked operably with the coding region, said control region comprising a plurality of promoters and at least one ribosome binding site, wherein at least one of said promoters is tac.
- 87. (Amended) A method of producing an amidated peptide product comprising the steps of:
- (a) culturing [the] an *E. coli* strain BLR host cell [of claim 35] <u>transformed with</u> an expression vector which comprises a gene for expressing the peptide product in a culture medium wherein the peptide product includes a C-terminal glycine;
  - (b) recovering said peptide product from said culture medium; and
- (c) converting said peptide product to [an] the amidated peptide by converting said C-terminal glycine to an amino group.

### REMARKS

By this Preliminary Amendment, Applicants have canceled claims 1-85, 88-90, 95 and 98-101 and amended claims 86 and 87. Accordingly, claims 86, 87, 91-94, 96 and 97 are now pending and under consideration in the present application. Applicants maintain that the above amendments raise no issue of new matter.

An Information Disclosure Statement is submitted herewith.

In light of the foregoing, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited.

#### EXPRESS MAIL CERTIFICATE

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail Post Office to Addressee (mail label #EL583735482US) in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on February 9, 2001:

Dorothy Jenkins

Name of Person Mailing Correspondence

February 9, 2001

Date of Signature

WOG/CCA:lac

Respectfully submitted,

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